Complete Summary

GUIDELINE TITLE

Role of imaging in cancer of the cervix.

BIBLIOGRAPHIC SOURCE(S)

Hricak H, Akin O, Sala E, Fleischer AC, Bohm-Velez M, Fishman EK, Mendelson E, Thurmond A, Goldstein S, Expert Panel on Women's Imaging. Role of imaging in cancer of the cervix. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 6 p. [70 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Hricak H, Mendelson E, Bohm-Velez M, Bree R, Finberg H, Fishman EK, Laing F, Sartoris D, Thurmond A, Goldstein S. Role of imaging in cancer of the cervix. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun 1;215(Suppl):925-30.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

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METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Cervical carcinoma (invasive cancer of the cervix)

GUIDELINE CATEGORY

Evaluation Risk Assessment

CLINICAL SPECIALTY

Nuclear Medicine Obstetrics and Gynecology Oncology Radiology

INTENDED USERS

Health Plans Hospitals Managed Care Organizations Physicians Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for cervical carcinoma

TARGET POPULATION

Patients with cervical carcinoma

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Magnetic resonance imaging (MRI)
- 2. Chest x-ray
- 3. Computed tomography (CT)
- 4. Pelvis ultrasound
- 5. Abdominal ultrasound
- 6. Endovaginal ultrasound
- 7. Nuclear medicine (NUC), bone scan
- 8. Intravenous urogram (IVU)
- 9. Barium enema (BE), x-ray, colon
- 10. Positron emission tomography (PET)

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1 to 9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are

unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by this Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A published cost analysis was reviewed. This analysis showed that MRI can be a cost-effective staging technique. In a study of patients with cervical cancer, those who underwent MRI as the initial procedure for staging required fewer tests and procedures compared with those who underwent standard clinical imaging.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Invasive Cancer of the Cervix

Variant 1: FIGO stage Ib.

Radiologic Exam Procedure	Appropriateness Rating	Comments
MRI	8	
X-ray, chest	5	
СТ	5	As spiral techniques evolve, the role of CT will be reassessed.

Radiologic Exam Procedure	Appropriateness Rating	Comments
PET	4	
US, pelvis	1	
US, abdomen	2	
US, endovaginal	2	
NUC, bone scan	1	
Intravenous urogram (IVU)	1	
X-ray, colon, barium enema (BE)	1	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 2</u>: FIGO stage Ib, tumor size >2 cm.

Radiologic Exam Procedure	Appropriateness Rating	Comments
MRI	8	
X-ray, chest	5	
СТ	5	
PET	4	
US, pelvis	2	
US, abdomen	2	
US, endovaginal	2	
NUC, bone scan	1	
Intravenous urogram (IVU)	1	
X-ray, colon, barium enema (BE)	1	
Appropriateness Criteria Scale		

Radiologic Exam Procedure	Appropriateness Rating	Comments
1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 3</u>: FIGO stage Ib, tumor size >3 cm.

Radiologic Exam Procedure	Appropriateness Rating	Comments
MRI	8	
X-ray, chest	5	
СТ	5	
PET	5	
US, pelvis	2	
US, abdomen	2	
US, endovaginal	2	
NUC, bone scan	1	
Intravenous urogram (IVU)	1	
X-ray, colon, barium enema (BE)	1	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 4</u>: FIGO stage greater than Ib.

Radiologic Exam Procedure	Appropriateness Rating	Comments
MRI	8	
X-ray, chest	8	

Radiologic Exam Procedure	Appropriateness Rating	Comments
СТ	7	
PET	7	
US, pelvis	2	
US, abdomen	2	
US, endovaginal	2	
NUC, bone scan	2	
Intravenous urogram (IVU)	1	
X-ray, colon, barium enema (BE)	1	

Appropriateness Criteria Scale
1 2 3 4 5 6 7 8 9
1 = Least appropriate 9 = Most appropriate

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Cervical cancer is the third most common gynecological malignancy. It is estimated that during 2004 there will be approximately 10,520 new cases of cervical cancer and 3,900 deaths from this disease in the United States. Between 1959-61 and 1989-91, there has been a 63% decrease in the mortality of cervical cancer. This improvement in mortality has been attributed to the development of the Papanicolaou smear, and only minor improvement has been achieved in the survival rate for invasive cervical cancer. Established risk factors for cervical cancer include early sexual activity, especially with multiple partners, cigarette smoking, immunosuppression, and infection with human papilloma viruses 16 and 18.

The prognosis of cervical carcinoma is primarily determined by the stage of disease, the volume of the primary tumor, and the histologic grade. The current staging system for cervical cancer is based on the FIGO classification. It defines the clinical staging system for cervical carcinoma based on clinical assessment including physical examination under anesthesia, colposcopy, endocervical curettage, hysteroscopy, cystoscopy, proctoscopy, IVU, BE, and X-rays of lungs and skeleton. Errors in clinical FIGO staging have been reported. When compared with surgical findings, FIGO staging errors are 28% in stage Ib disease and 50%-64% in stage IIa-IIb disease. Clinical evaluation underestimates the surgical stage in 15%-36% of patients. In clinically staged Ib disease, underestimation of tumor extent occurs in 21% and overestimation in 6% of patients. Inaccuracy in clinical staging is predominantly due to difficulties in evaluating parametrial and pelvic sidewall invasion, bladder or rectal wall invasion, metastatic spread, and in evaluating primary endocervical (endophytic) tumors. Aside from the inaccuracies

of clinical staging, evaluation of lymph node metastasis, which is an important prognostic factor and a determinant in treatment planning, is not included in the clinical staging system. In surgically treated stages Ib and IIa cervical cancer, survival rates decline from 85%-90% to 50%-55%, respectively, in the presence of metastatic lymph nodes. In spite of these limitations of clinical FIGO staging, modern cross-sectional imaging modalities such as US, CT, and MRI have not been incorporated into clinical staging. Among the most common arguments against the use of CT or MRI as staging tools are their high cost and unavailability universally.

Current Role of I maging

The most important issue in staging cervical cancer is to distinguish early disease (stages IA and IB) that can be treated with surgery from advanced disease that must be treated with radiation alone or combined with chemotherapy. Imaging modalities must be directed to solve this clinically important question. Conventional radiological studies such as excretory urography, BE, and lymphangiography are less commonly used today. However, there has been an increase in the use of cross-sectional imaging, particularly CT and MRI.

Plain chest radiographs are obtained as a staging procedure to identify pleural effusion or pulmonary metastasis, which occur in the late stages of cervical cancer. However, chest CT is superior to plain film in both occasions.

Excretory urography is a sensitive test in the detection of urinary obstruction. However, a low incidence (2.4%) of urinary obstruction in stage Ib disease argues against the routine use of this test. Discontinuation of the routine use of BE, cystoscopy, and sigmoidoscopy has been suggested previously.

Transabdominal US can show the presence of hydronephrosis but has a limited role in the evaluation of local extent of the cervical cancer. Transrectal and transvaginal US have been used in the assessment of local disease but are limited in the detection of parametrial disease and pelvic side wall involvement due to poor soft-tissue contrast, small field of view, and operator dependence.

CT has staging accuracy ranging from 32% to 80% in cervical cancer. The sensitivity for parametrial invasion ranges from 17% to 100% with an average of 64%. Specificity ranges from 50% to 100% with an average of 81%. There is a consensus in the literature that the value of CT increases with higher stages of disease, and that CT has limited value (a positive predictive value of 58%) in evaluating early parametrial invasion. However, CT has an accuracy of 92% in depicting advanced disease. The major limitation of CT in local staging is its inadequate differentiation between tumor and normal cervical stroma or parametrial structures. Therefore, CT is mainly used in advanced disease and in the assessment of lymph nodes. The positive predictive value of CT for nodal involvement is 65% with a negative predictive value of 86%. CT is also performed to detect distant metastases, for radiotherapy planning, and for guiding interventional procedures.

MRI is very accurate in determining tumor size and location (exophytic or endocervical), the depth of stromal invasion, and the local extension of the tumor. MRI is superior to clinical evaluation in assessing tumor size, and MRI

measurements are within 0.5 cm of the surgical size in 70% to 90% of cases. The staging accuracy of MRI ranges from 75% to 96%. The sensitivity of MRI in evaluating parametrial invasion is 69%, and the specificity is 93%. In studies that compare MRI and CT for the evaluation of parametrial invasion, MRI was superior to CT. In evaluating nodal disease, the sensitivity and specificity of MRI, 50% and 95% respectively, are similar to those of CT. In assessing local tumor invasion, T2-weighted images are superior to contrast-enhanced T1-weighted images. MRI can be a cost-effective staging technique. In a study of patients with cervical cancer, those who underwent MRI as the initial imaging procedure for staging required fewer tests and procedures compared with those who underwent standard clinical imaging.

Lymphangiography

Although lymphangiography has been routinely used in the past for the pretreatment evaluation of lymph node metastases, it has been mostly replaced in this role by CT and MRI. Single studies that have compared lymphangiography and CT have shown similar accuracy (72%-91% and 71%-88%, respectively) for both modalities. CT may have a slightly higher specificity than lymphangiography (88%-95% versus 59%-93%), but lymphangiography is more sensitive than CT (63%-88% versus 53%-72%), especially in early stages (I-II) of disease. A meta-analysis compared the utility of lymphangiography, CT and MRI in patients with cervical cancer. Although summary-receiver-operator characteristics revealed no significant differences in the overall performance, there was a trend toward better performance for MRI than for lymphangiography or CT.

Although the current use of PET in the initial evaluation of cervical cancer is still under investigation, PET can be used to assess nodal disease and tumor recurrence. In the detection of metastatic lymph nodes in patients with cervical cancer, PET has been reported to have a sensitivity of 91% and a specificity of 100%, which are higher than those for MRI (73% and 83% respectively). Another study showed that when abdominal CT is negative, PET has a sensitivity of 85.7%, a specificity of 94.4%, and an accuracy of 92% for detecting para-aortic lymph node metastasis in patients with advanced cervical cancer. For detecting recurrence, PET has been reported to have a sensitivity and specificity of 85.7% to 90.3% and 76.1% to 86.7%, respectively. PET has added value in patients with recurrent cervical cancer who undergo salvage therapy as it can provide precise restaging information. A recent study suggests that abnormal PET findings were the most significant prognostic factor for developing metastasis and death from cervical cancer.

Abbreviations

- BE, barium enema
- CT, computed tomography
- FIGO, International Federation of Gynecology and Obstetrics
- IVU, intravenous urogram
- MRI, magnetic resonance imaging
- NUC, nuclear medicine
- PET, positron emission tomography
- US, ultrasound

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS.

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for accurate prognosis of cervical carcinoma

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to quide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Hricak H, Akin O, Sala E, Fleischer AC, Bohm-Velez M, Fishman EK, Mendelson E, Thurmond A, Goldstein S, Expert Panel on Women's Imaging. Role of imaging in cancer of the cervix. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 6 p. [70 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2005)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUI DELI NE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Women's Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Hedvig Hricak, MD, PhD; Oguz Akin, MD; Evis Sala, MD, PhD; Arthur C. Fleischer, MD; Marcela Böhm-Vélez, MD; Elliot K. Fishman, MD; Ellen Mendelson, MD; Amy Thurmond, MD; Steven Goldstein, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUI DELI NE STATUS

This is the current release of the guideline.

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The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology Web site.

ACR Appropriateness Criteria® Anytime, Anywhere $^{\text{TM}}$ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191; Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the <u>American College of Radiology (ACR) Web site</u>.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 28, 2000. The information was verified by the guideline developer on January 25, 2001. This NGC summary was updated by ECRI on February 1, 2006.

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